The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information

YODA Project (Protocol) ID:	2014-0401
Date:	17 December 2014
Product Name:	Infliximab
Therapeutic Area:	Immunology
Product Class:	Tumor necrosis factor (TNF) blocker
Condition(s) Studied:	Crohn's disease
Protocol Number(s) and Title(s):	NCT00094458 / C0168T67 Multicenter, Randomized, Double-Blind, Active Controlled Trial Comparing REMICADE (Infliximab) and REMICADE Plus Azathioprine to Azathioprine in the Treatment of Patients With Crohn's Disease Naive to Both Immunomodulators and Biologic Therapy

Part 2: Data Availability

Question:	Response:
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments: N/A	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes
Comments: N/A	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments: N/A	
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).	Yes
Comments: N/A	

Part 3: Data Availability Summary

Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	Yes

Part 4: Proposal Review

Question:	Response:
Summary-level CSR data is appropriate for the proposed analysis.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments: CRP was only collected at baseline and Week 26. CRP was not collected at Week 50.	